Acceptance criteria: The R_F values of the two principal spots of the *Sample solution* correspond to those of the *Standard solution.*

ASSAY

• **ACETAMINOPHEN**

Mobile phase: Methanol and water (3:7)

Standard solution: 0.48 mg/mL of USP Acetaminophen RS in *Mobile phase*

Sample solution: Nominally 0.48 mg/mL of acetaminophen in *Mobile phase*, prepared by adding a volume of Oral Solution, equivalent to 120 mg of acetaminophen, to a 250-mL volumetric flask. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability.*)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of acetaminophen from the *Sample solution*

r_S = peak response of acetaminophen from the *Standard solution*

C_S = concentration of USP Acetaminophen RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of acetaminophen in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

• **CODEINE PHOSPHATE**

Mobile phase: Dissolve 4.44 g of docusate sodium in 1000 mL of a mixture of methanol, tetrahydrofuran, phosphoric acid, and water (600:40:1:360) with stirring, and pass through a membrane filter of 0.45-µm or finer pore size.

Diluent: Methanol and water (3:7)

Standard solution: 0.12 mg/mL of USP Codeine Phosphate RS in *Diluent*

Sample solution: Nominally 0.12 mg/mL of codeine phosphate hemihydrate in *Diluent*, prepared by adding a volume of Oral Solution, equivalent to 12 mg of codeine phosphate hemihydrate, to a 100-mL volumetric flask. Dilute with *Diluent* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability.*)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of codeine phosphate hemihydrate ($C_{18}H_{21}NO_3 \cdot H_3PO_4 \cdot {}^1/_2H_2O$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of codeine phosphate from the *Sample solution*

r_S = peak response of codeine phosphate from the *Standard solution*

C_S = concentration of USP Codeine Phosphate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of codeine phosphate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of codeine phosphate hemihydrate, 406.37

M_{r2} = molecular weight of anhydrous codeine phosphate, 397.37

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩

For single-unit containers

Acceptance criteria: Meets the requirements

• **DELIVERABLE VOLUME** ⟨698⟩

For multiple-unit containers

Acceptance criteria: Meets the requirements

IMPURITIES

• **4-AMINOPHENOL IN ACETAMINOPHEN-CONTAINING DRUG PRODUCTS** ⟨227⟩: Meets the requirements

SPECIFIC TESTS

• **pH** ⟨791⟩: 4.0–6.1

• **ALCOHOL DETERMINATION** ⟨611⟩, *Method II* (if present): 90.0%–120.0% of the labeled quantity of alcohol (C_2H_5OH), acetone being used as the internal standard

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store at controlled room temperature.

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Acetaminophen RS

USP Codeine Phosphate RS

Acetaminophen and Codeine Phosphate Oral Suspension

DEFINITION

Acetaminophen and Codeine Phosphate Oral Suspension is a suspension of Acetaminophen and Codeine Phosphate in a suitable aqueous vehicle. It contains NLT 90.0% and NMT 110.0% of the labeled amount of acetaminophen ($C_8H_9NO_2$) and codeine phosphate hemihydrate ($C_{18}H_{21}NO_3 \cdot H_3PO_4 \cdot {}^1/_2H_2O$).

IDENTIFICATION

• **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution,* as obtained in the *Assay.*